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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,852	10/22/2003	Kimberly A. McGuigan	103864.142 US1	4225

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NEW YORK, NY 10022		

EXAMINER	
LUBIN, VALERIE	

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
05/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/689,852	Applicant(s) MCGUIGAN ET AL.	
	Examiner VALERIE LUBIN	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/22/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

1. Applicant's election without traverse of Group I: claims 1-8 in the reply filed on 02/20/2009 is acknowledged.

Claims 1-8 and 23-38 are pending.

For reference purposes, the document paper number is 20090505.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Claims 2 and 28 recite "summing a total supply of an associated compliance medication prescribed..." However, Applicant does not provide a description of such total supply in the respective specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 2 and 28 are ambiguous as they recite medication supply weights which in claim 1 are recited as a data element different from a regression coefficients; however Applicant's specification describes such weights as the same as the regression coefficients.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-8 and 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camarda et al. U.S. Patent No. 6,578,003 in view of Prasad et al. U.S. Patent No. 7,444,291.

10. With respect to claim 1, Camarda discloses a method comprising the steps of: 1) retrieving by a computer system pharmacy claims from a pharmacy claims database (Col. 7 lines 11-20) and processing by the computer system said pharmacy claims to identify any chronic conditions possessed by said individual (Col. 6 lines 34-44); (2) processing said pharmacy claims to identify any compliance medications prescribed to said individual (Col. 6 lines 36-37; (4) generating a compliance medication score by summing products of regression coefficients for each compliance medication prescribed to said individual with associated medication supply weights, or compliance (Col. 7 lines 57-62).

Camarda does not disclose (3) generating a chronic condition score by summing regression coefficients for each chronic condition possessed by said individual; (5) generating a modified chronic condition score by multiplying said chronic condition score by an overall chronic condition regression coefficient and (6) further modifying said modified chronic condition score by subtracting a no-claims weight from said chronic condition score, if said individual has no pharmacy claims. However, Prasad discloses calculating a chronic condition score ("burden of illness score" in col. 11 lines 54-60; col. 14 lines 25-28). The data or variables used to determine and modify such chronic score is a mere substitution of known elements for other known elements that yield a predictable result (Ex parte Smith, 83 USPQ2d 1509 (Bd. Pat. App. & Int. 2007)). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Camarda and Prasad to determine a chronic score in order to segment patients based score and further assist those who do not meet a threshold score. Furthermore, with regards to the sixth limitation, it is an optional step, and according to the MPEP, "Language that suggests or makes optional but does not

require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation” (MPEP 2106.II.C).

Camarda and Prasad do not specifically recite (7) generating by said computer system said risk index by summing said modified chronic condition score and said compliance medication score; however Examiner takes Official Notice that generating a risk index was old and well known in the art at the time the invention was made. It would therefore have been obvious to one of ordinary skill in the art to combine the prior art with the scores provided by Camarda and Prasad in order to identify patients with a certain risk index and select them for further intervention.

Claims 2, 3, 8, 27-29, 34 are rejected under the analysis of claim 1.

11. Claims 4, 5 and 7 are rejected under the analysis of claim 1, as they are directed to non-functional material describing data variables and do not further limit the method of claim 1 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claims 30, 31 and 33 are rejected under the above analysis.

12. Claim 6 is rejected under the analysis of claim 1, as it is an optional step which does not further limit the method of claim 1. See MPEP 2106.II.C.

Claim 32 is rejected under the analysis of claim 6.

13. Claim 23 is rejected, as Camarda recites the computer retrieving patient information comprising patient eligibility data (Col. 7 lines 20-25). Camarda does not specifically recite

generating a risk index responsive to the patient eligibility data; however, Examiner takes Official Notice that generating a risk index based on patient data was old and well known in the art at the time the invention was made. It would therefore have been obvious to one of ordinary skill in the art to combine the prior art with the teachings of Camarda and Prasad to derive a risk index based on patient eligibility data, because such eligibility data predetermines whether a patient with a high risk index will be able to be part of the intervention.

Claim 35 is rejected under the analysis of claim 23.

14. Claim 24 is rejected, as Camarda recites determining a clinical case identification with respect to the patient (Col. 15 lines 6-26). Based on certain scores, Camarda's invention identifies patients who need to be part of the intervention; the computer generates the intervention (e-mail, letter, etc) and sends it to the patients.

Claim 36 is rejected under the analysis of claim 24.

15. For claim 25, Prasad recites determining variations in at least one of estimated total healthcare costs and utilization by the patient (Fig. 1 Element 18; col. 3 lines 3-12; col. 11 lines 57-60). It would have been obvious to combine the teachings of Camarda and Prasad to determine variation in total healthcare costs and utilization by a patient in order to better budget and prepare for assisting patients.

Claim 37 is rejected under the analysis of claim 25.

16. With regards to claim 26, Camarda recites determining whether to generate comparable groups which may have differing rates of chronic illness (Col. 10 lines 9-36), and adjusting for factors including at least one adverse and favorable selection in at least one health plans, programs and health-related interventions (Abstract "Based on this score...are sent the champion interventions").

Claim 38 is rejected under the analysis of claim 26.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a) Iliff U.S. Patent No. 6,468,210 discloses generating a disease score

b) Pollak et al. U.S. Patent No. 6,410,335 and Kamijo U.S. Patent No. 7,136,055

disclose generating a risk index.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295.

The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VL

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626